The unofficial revised text of the regulation is only an informative work tool, in respect of which the authority is not liable for compensation or otherwise.

The unofficial text includes:

- Tariff of the Agency of the Republic of Slovenia for Medicinal Products and Medical Devices (Official Gazette of the Republic of Slovenia, No. 209/21 of 31 December 2021),
- Amendments to the Tariff of the Agency of the Republic of Slovenia for Medicinal Products and Medical Devices

TARIFF
of the Agency of the Republic of Slovenia for Medicinal Products and Medical Devices

I. GENERAL PROVISIONS

Article 1
(Type of services)

(1) This List of Rates lays down the fees for services provided by the Public Agency of the Republic of Slovenia for Medicinal Products and Medical Devices (hereinafter: JAZMP) for private and legal entities, for the costs of performing administrative tasks that are part of public powers and are carried out by the JAZMP, and for the costs of performing professional tasks and services within the JAZMP's powers.

(2) The holder of the marketing authorisation for a medicinal product or a marketing authorisation for a parallel-imported medicinal product and the holder of a licence to pursue the activity issued by the JAZMP shall also pay an annual fee for the costs of monitoring the medicinal product on the market, which refer to an individual medicinal product as per the number of its pharmaceutical forms or strengths.

(3) Fees to be charged by the JAZMP shall include:

1. annual fees for monitoring a medicinal product with marketing authorisation on the market and for monitoring activities relating to medicinal products;
2. fees for the issue, variation and termination of a manufacturing authorisation for medicinal products;
3. fees for the issue of certificates relating to the verification of conformity with good manufacturing practice among medicinal product manufacturers;
4. fees for the issue, variation and termination of a wholesale distribution authorisation and announcement of a wholesaler established in the European Union;
5. fee for the issue of a certificate on good distribution practice of medicinal products and active substances;
6. fees for the issue, variation and termination of a retail sale authorisation for medical products in specialised shops for the issue of OTC medical products;
7. fees for entry into, amendment of and removal from the register of manufacturers, wholesalers and importers of active substances;
8. fees for entry into, amendment of or removal from the register of agents selling medicinal products and active substances;
9. fees for entry into, amendment of and removal from the register of medical sales representatives when advertising medical products;
10. fees for the procedure of approving clinical trials for a medicinal product and evaluating clinical trial performance;
11. fees for the procedure of announcing a non-interventional clinical trial or non-interventional study or the issue of preliminary approval for a non-interventional clinical trial or non-interventional study;
12. fees for the issue of an authorisation for the compassionate use of medicinal products;

13. fees for the issue, line extension, renewal, variation, transfer and withdrawal of a marketing authorisation for a medicinal product for human use and a marketing authorisation for a veterinary medicinal product;
14. fees for the assessment of an updated Periodic Safety Update Report (PSUR) for a medicinal product with unlimited marketing authorisation;
15. fees for a review of training materials for safe and effective use of medicinal products and for other amendments to information on a medical product;
16. fees for an application for listing a medicinal product among interchangeable medicinal products under an independent procedure;
17. fees for the issue, renewal, variation, transfer and withdrawal of a marketing authorisation for herbal medicinal products;
18. fees for the issue, renewal, variation, transfer and withdrawal of a marketing authorisation for homeopathic medicinal products;
19. fees for the issue of a temporary marketing authorisation and the entry or import of medicinal products with no marketing authorisation;
20. fees for the issue of an authorisation for the entry or import and removal or export of illicit drugs in groups II and III and for sealing the register of medicinal products, which are illicit drugs in groups II, III a and III c;
21. fees for marketing authorisation for a parallel-imported medicinal product and a certificate on the parallel distribution of medicinal products;
22. fees for the issue, renewal, variation and revocation of a marketing authorisation for a parallel imported medicinal product;
23. fees for approval of individual deviations from the conditions of marketing authorisation (OOS) and for the preservation of a medicinal product's marketing authorisation;
24. fees for approval of the use of foreign-language-labelled packaging with a label in Slovenian attached;
25. fees for determining the elements in blue box and the national identifier of medical products, for which marketing authorisation was obtained in accordance with the centralised procedure;
26. fees for the deferment of cancellation of a marketing authorisation;
27. fee for the approval of conducting a campaign for vaccination with necessary data on vaccines;
28. fees for the definition of a product;
29. fees for the determination of an extraordinary higher allowed price of a medicinal product;
30. fees for the determination of the maximum allowed price of a medicinal product;
31. fees for announcing business donations of medicinal products;
32. fees for the issue, variation and withdrawal of a human tissue and cell supply authorisation;
33. fees for the issue, variation and withdrawal of a blood supply authorisation;
34. fees for the issue, variation and withdrawal of an authorisation for non-routinely prepared advanced therapy medicinal products;
35. fees for entry into, amendment to and removal from the register of doctors and veterinarians who use non-routinely prepared advanced therapy medicinal products in their practice;
36. fees for the announcement of galenic medicinal products and the approval of risk assessments for the manufacture of galenic medicinal products, as well as for the preparation of extemporaneous medicinal products.

(4) The JAZMP shall charge for the performance of the following professional tasks and services:

1. expert training, lecture, workshop and consultation;
2. consulting;
3. specialisation and mentoring;
4. travel and other expenses of experts and pharmaceutical inspectors when performing their tasks;
5. publishing;
6. photocopying, printing and scanning;
7. issuing additional copies and duplicates and confirmation of the finality of individual administrative acts;
8. other professional tasks;
9. issue of reminders for outstanding liabilities.

Article 2
(Rate levels)

(1) The rates shall be laid down in points. The amount for payment shall be the point value multiplied by the number of points.

(2) The value of one point shall be EUR 5.50 excluding value added tax. The value of one point may be verified annually, i.e. based on actual costs relating to the performance of tasks and services herein. Any change in the value of one point shall be adopted by the Board of JAZMP with the founder's prior consent. The new value of the point shall be published in the Official Gazette of the Republic of Slovenia.

II. FEES

Article 3
(Payment obligations, methods and deadlines)

(1) The fee shall be subject to payment by submitting an application or upon receipt of a call for payment or notification on how to pay the fee from the JAZMP.

(2) The JAZMP shall send a notification on such payment method to the applicant's email address, which is included in the application form. The notification on the fee's payment method shall include at least the information on the applicant, the received application, the object of the charged fee (products), the fee amount, the reference number and other information required for payment. The notification on the payment method of the fee shall be produced by the person responsible for the procedure from the information system intended for managing procedures and keeping records. The applicant shall settle the fee for the procedures within 15 days upon receiving the notification on how to pay the fee to the JAZMP sub-account.

(3) An annual fee shall be settled within 15 days after the receipt of the payment notification of annual fees. The JAZMP shall submit notifications for the payment of annual fees to the authorisation holders no later than by 31 March of the current year for all applicable authorisations as of 1 January of the current year.

(4) When settling the fee, the applicant shall provide the reference number stated in the notification on the payment method of the fee.

(5) In the case of non-payment of the fee, the JAZMP may charge statutory late payment interest to the applicant.

Article 4
(Annual fees)

Annual fees for monitoring a medicinal product on the market and for monitoring activities relating to medicinal products shall be as follows:

1. for a marketing authorisation for a medicinal product or a parallel imported medicinal product in any pharmaceutical form: 60 points but not less than 180 points and not more than 9,600 points;
2. for an individual marketing authorisation for a veterinary medicinal product or a parallel imported veterinary medicinal product in any pharmaceutical form: 60 points;
3. for an individual marketing authorisation for a herbal medicinal product in any pharmaceutical form: 60 points;
4. for an individual marketing authorisation for a homeopathic medicinal product in any pharmaceutical form: 14 points;
5. for an individual manufacturing authorisation for a medicinal product: 240 points;
6. for an individual wholesale distribution authorisation for medicinal products: 240 points;
7. for an individual retail sale authorisation for medicinal products in specialised shops: 120 points;
8. for an individual certificate of entry into the register of manufacturers, wholesalers and importers of active substances: 240 points;
9. for an individual certificate of entry into the official register of a notified wholesaler of medicinal products, who obtained a marketing authorisation for medicinal products in another European Union Member State: 120 points;
10. for an individual certificate of the entry into the register of agents selling medicinal products and active substances: 120 points;
11. for authorisation to perform activities of blood supply: 120 points;

12. for individual authorisation to pursue activities of supplying human tissues and cells: 200 points;
13. for an authorisation for an advanced therapy medicinal product prepared on a non-routine basis: 200 points.

Article 5
(Fees relating to medicinal product manufacturing)

Fees for the issue, variation and termination of a manufacturing authorisation for medicinal products shall be as follows:

1. for the issue of an authorisation for medicinal product manufacturing based on verification of compliance with good manufacturing practice per day of an expert committee's inspection at the applicant's premises: 380 points;
2. for the consideration of a variation when reassessment of compliance with good manufacturing practice is not necessary and the variation requires a variation of the medicinal product manufacturing authorisation: 75 points;
3. for the consideration of a variation, when reassessment of compliance with good manufacturing practice is necessary and the variation requires a variation of the medicinal product manufacturing authorisation per day of an expert committee's inspection at the applicant's individual manufacturing locations: 305 points;
4. for the issue of a compliance assessment for the manufacturing of medicinal products, when reassessment of compliance with good manufacturing practice is necessary and the variation does not require a variation of the medicinal product manufacturing authorisation per day of an expert committee's inspection at the applicant's premises: 305 points;
5. for the termination of medicinal product manufacturing authorisation at the request of the authorisation holder: 40 points;
6. for the issue of a compliance assessment for the manufacturing of medicinal products, when reassessment of compliance with good manufacturing practice is not necessary and the variation does not require a medicinal product manufacturing authorisation: 75 points;
7. for entry into the register of persons responsible for the release of individual medicinal product series: 20 points;
8. for an amendment to the register entry of persons responsible for the release of individual medicinal product series: 20 points;
9. for the removal from the register of persons responsible for the release of individual medicinal product series: 20 points.

Article 6
(Fees relating to the inspection of good manufacturing practice and certificates of quality and status of medicinal products)

(1) Fees for the inspection of good manufacturing practice at a manufacturing site of a medicinal product and an active substance, and fees for the issue of certificates for the manufacturer's good manufacturing practice shall be as follows:

1. for the assessment of compliance with good manufacturing practice in a procedure for obtaining marketing authorisation at the applicant's premises per pharmaceutical supervisor/day: 400 points;
2. for the assessment of compliance with good manufacturing practice abroad at the proposal of a legal or natural entity per pharmaceutical supervisor/day: 400 points;
3. for the issue of a certificate of good manufacturing practice compliance abroad for medicinal products and active substances: 100 points.

(2) Fee for the issue of certificates of quality and status of medicinal products entering international trade (CPP, certificate of the manufacture and sales of a medicinal product in compliance with GMP, certificate of the regulatory status of the medicinal product, statement that the medicinal product is manufactured in Slovenia): 50 points.

(3) In addition to the fees referred to in points 1 and 2 of the preceding paragraph, the applicant shall also cover other costs of pharmaceutical supervisors in accordance with Article 52 hereof.

Article 7
(Fees relating to wholesale distribution authorisation for medicinal products)

(1) Fees for the issue, variation and termination of wholesale distribution authorisation shall be as follows:

1. for the issue of wholesale distribution authorisation for medicinal products based on verification of compliance with good distribution practice per day of expert committee inspection at the applicant's premises: 210 points;
2. for the consideration of a variation, when reassessment of compliance with good distribution practice is not necessary and the variation requires a variation of the wholesale distribution authorisation for medicinal products: 55 points;
3. for the consideration of a variation when reassessment of compliance with good distribution practice is necessary and when the variation requires a variation of the wholesale distribution authorisation for medicinal products per day of expert committee inspection at the applicant's premises: 155 points;
4. for the issue of an assessment of compliance with the requirements for the wholesale of medicinal products including an inspection, when reassessment of compliance with good distribution practice is necessary and the variation does not require a change in the wholesale distribution authorisation for medicinal products per day of expert committee inspection at the applicant's premises: 155 points;
5. for the issue of a certificate of good distribution practice: 100 points;
6. for the termination of a wholesale distribution authorisation for medicinal products at the request of the authorisation holder: 40 points;
7. for entry into the register of persons responsible for the adoption of medicinal products: 20 points;
8. for an amendment to the entry in the register of persons responsible for the adoption of medicinal products: 20 points;
9. for the removal from the register of persons responsible for the adoption of medicinal products: 20 points;
10. for entry into the official register of a notified wholesaler of medicinal products who obtained a marketing authorisation for medicinal products in another European Union Member State: 150 points;
11. for an amendment to the entry in the official register of a notified wholesaler of medicinal products, who obtained a marketing authorisation for medicinal products in another European Union Member State: 150 points;
12. for removal from the official register at the request of a notified wholesaler of medicinal products who obtained a marketing authorisation for medicinal products in another European Union Member State: 20 points.

Article 8
(Fees for retail sale authorisation for medicinal products in specialised shops)

Fees for the issue, amendment and termination of a retail sale authorisation for medicinal products in specialised shops shall be as follows:

1. for the issue of retail sale authorisation for medicinal products in specialised shops based on verification of compliance with requirements per day of expert committee inspection: 305 points;
2. for the consideration of a variation, when reassessment of compliance with requirements is not necessary and the variation requires a change in the retail sale authorisation for medicinal products in a specialised shop: 75 points;
3. for the assessment of compliance with requirements with regard to the retail sale of medicinal products in specialised shops, when reassessment of compliance with the requirements is necessary and the variation does not require a change in the retail sale authorisation for medicinal products in specialised shops per day of expert committee inspection: 230 points;
4. for the consideration of a variation when a reassessment of compliance with the requirements is necessary and the variation requires a change in the retail sale authorisation for medicinal products in specialised shops per day of expert committee inspection: 230 points;
5. for the termination of the retail sale authorisation for medicinal products in a specialised shop at the request of the authorisation holder: 40 points.

Article 9
(Fees for registers of manufacturers, wholesalers and importers of active substances)

Fees for registers of manufacturers, wholesalers and importers of active substances shall be as follows:

1. for entry into the register of manufacturers, wholesalers and importers of active substances: 150 points;

2. for entry into the register of manufacturers, wholesalers and importers of active substances per day of expert committee inspection: 225 points;
3. for an amendment to the entry in the register of manufacturers, wholesalers and importers of active substances: 75 points;
4. for an amendment to the entry in the register of manufacturers, wholesalers and importers of active substances per day of expert committee inspection: 125 points;
5. for removal from the register of manufacturers, wholesalers and importers of active substances: 20 points;
6. for the consideration of annual reports of a manufacturer, wholesaler and an importer of active substances: 40 points;
7. for the issue of an assessment of compliance with the requirements for entry into the register of manufacturers, wholesalers and importers of active substances where the amendment does not require a change in the entry in the register per day of expert committee inspection at the applicant's premises: 125 points.

Article 10
(Fees for brokerage of medicinal products and active substances)

Fees for brokerage of medicinal products and active substances shall be as follows:
1. for entry into the register of agents selling medicinal products and active substances: 40 points;
2. for an amendment to the entry in the register of agents selling medicinal products and active substances: 40 points;
3. for entry into the register of agents selling medicinal products and active substances: 20 points.

Article 11
(Fees for the entry into, amendment to and removal from the register of medical sales representatives when advertising medicinal products)

Fees for the entry into, amendment to and removal from the register of medical sales representatives when advertising medicinal products shall be as follows:
1. for the entry of a medical sales representative into the register: 20 points;
2. for an amendment to the entry of a medical sales representative in the register: 20 points;
3. for the removal of a medical sales representative from the register: 20 points.

Article 12
(Fees for clinical trial and non-interventional trial of medicinal products or for non-interventional study)

(1) Fees for the procedure of announcing or approving a clinical trial for a medicinal product and fees for the supervision of the implementation of clinical trials in compliance with good clinical practice shall be as follows:
1. for the announcement or approval of clinical trials for a medicinal product based on an assessment from another European Union Member State: 190 points;
2. for the announcement or approval of clinical trials for a medicinal product based on an assessment of protocol: 1,210 points;
3. for the announcement of an amendment to a clinical trial for a medicinal product: 40 points;
4. for an issue of consent to the protocol of non-interventional trial of a medicinal product or non-interventional study carried out at the request of the JAZMP and taking place only in the Republic of Slovenia: 305 points;
5. for announcing a non-interventional trial of a medicinal product or non-interventional study: 75 points;
6. for announcing a major change in the protocol of non-interventional trial of a medical product or non-interventional study carried out at the request of the JAZMP and taking place only in the Republic of Slovenia: 35 points;
7. for the assessment of a clinical trial for compliance with good clinical practice at the proposal of a legal entity or a natural person per pharmaceutical supervisor/day: 305 points;
8. for the assessment of a clinical trial for compliance with good clinical practice in the procedure for marketing authorisation acquisition per pharmaceutical supervisor/day: 305 points.

(2) In addition to the fees referred to in points 7 and 8 of the preceding paragraph, the applicant shall also cover other costs of pharmaceutical supervisors in accordance with Article 52 hereof.

(3) Fees for the procedure of approving a clinical trial for a veterinary medicinal product shall be as follows:

1. for the approval of a clinical trial for a medicinal product based on protocol assessment: 150 points;
2. for the approval of an amendment to a clinical trial for a medicinal product: 40 points;
3. for announcing a non-interventional clinical trial: 75 points;
4. for announcing an amendment to a non-interventional clinical trial: 35 points;

(4) Fees relating to the procedure of announcement or approval of a clinical trial for a medicinal product among a paediatric population and in orphan medicines shall amount to half the value of individual fees referred to in paragraph one of this Article.

(5) Fees relating to the procedure of announcement or approving of a clinical trial for a medicinal product and announcing an important amendment to a clinical trial for a medicinal product for human use, with sponsors being non-profit businesses and private individuals (non-commercial clinical trial) shall amount to a half of the value of individual fees from paragraph one of this Article.

(6) Fees relating to the procedure of obtaining authorisation for compassionate use shall not be charged.

Article 12a

(Fees for clinical trials of medicinal products for human use in accordance with Regulation 536/2014/EU)

(1) Fees for procedures for clinical trials of medicinal products for human use in accordance with Regulation (EU) 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158 of 27 May 2014, p. 1), last amended by Commission Delegated Regulation (EU) 2022/2239 of 6 September 2022 amending Regulation (EU) No. 536/2014 of the European Parliament and the Council as regards labelling requirements for unauthorised investigational and unauthorised auxiliary medicinal products for human use (OJ L No. 294 of 15 November 2022, p. 5) and the distribution of fees between JAZMP and the Medical Ethics Commission are set out in Annex 1, which forms an integral part of the Tariff.

(2) For the procedures for monitoring the safety of a medicinal product in a clinical trial for each starting year of conducting a clinical trial in the Republic of Slovenia, the applicant of the procedure referred to in the preceding paragraph of this Article shall pay a fee of 180 points.

(3) The fees relating to the procedure for the authorisation of a clinical trial and the authorisation of a substantial modification of a clinical trial in the paediatric population shall be half the value of the individual fee referred to in paragraph one of this Article.

(4) Fees related to the supervision of the conduct of clinical trials in accordance with good clinical practice shall be as follows:

- for the assessment of compliance of a clinical trial with good clinical practice when proposed by a legal entity or a natural person per pharmaceutical supervisor/day: 305 points;

- for the assessment of compliance of a clinical trial with good clinical practice in the procedure for marketing authorisation acquisition per pharmaceutical supervisor/day: 305 points.

(5) In addition to the fees referred to in the preceding paragraph of this Article, the applicant shall also cover other costs of pharmaceutical supervisors in accordance with Article 52 hereof.

Article 13
(Fees for obtaining a marketing authorisation for medicinal product for human use)

(1) The JAZMP shall issue marketing authorisations or carry out the following procedures:

1. national procedures (hereinafter: NP);
2. mutual recognition procedures in which the Republic of Slovenia is the reference member state (hereinafter: MRP-RMS);
3. mutual recognition procedures in which the Republic of Slovenia is the concerned member state (hereinafter: MRP-CMS);
4. decentralised procedures in which the Republic of Slovenia is the reference member state (hereinafter: DCP-RMS);
5. decentralised procedures in which the Republic of Slovenia is the concerned member state (hereinafter: DCP-CMS);
6. repeat use of a mutual recognition procedure after a completed MRP or DCP procedure in which the Republic of Slovenia is the reference member state (hereinafter: RUP-RMS).

(2) Fees for obtaining a marketing authorisation for medicinal product for human use shall be as follows:

1. for obtaining marketing authorisations pursuant to Articles 44 or 49 of the Act:
   a) NP: 2,055 points;
   b) MRP-CMS: 735 points;
   c) MRP-RMS: 5,985 points;
   d) RUP-RMS: 4,000 points;
   e) DCP-CMS: 735 points;
   f) DCP-RMS: 6,990 points;

2. for obtaining marketing authorisations pursuant to Article 47 of the Act~~in~~:
   a) NP: 2,000 points;
   b) MRP-CMS: 735 points;
   c) MRP-RMS: 5,695 points;
   d) RUP-RMS: 3,700 points;
   e) DCP-CMS: 735 points;
   f) DCP-RMS: 6,420 points;

3. for obtaining marketing authorisations pursuant to paragraphs one or six of Article 45 of the Act:
   a) NP: 1,775 points;
   b) MRP-CMS: 615 points;
   c) MRP-RMS: 4,995 points;
   d) RUP-RMS: 3,400 points;
   e) DCP-CMS: 615 points;
   f) DCP-RMS: 5,790 points;

4. for obtaining marketing authorisations pursuant to Article 50 of the Act:
   a) NP: 650 points;
   b) MRP-CMS: 510 points;
   c) MRP-RMS: 2,580 points;
   d) RUP-RMS: 1,700 points,
   e) DCP-CMS: 735 points;
   f) DCP-RMS: 4,190 points;

(3) Notwithstanding the preceding paragraph, the fee for obtaining a marketing authorisation for a medicinal product shall be reduced by 50% if:

- the medicinal product, with its active ingredient, pharmaceutical form and strength, is included in the list of essential medicinal products or indispensable medicinal products;

- the medicinal product has been brought in or imported in accordance with paragraph three of Article 20 of the Act during the 18 months preceding the submission of the application in question;

- there is no medicinal product with the same active substance in the same strength and pharmaceutical form with a marketing authorisation in circulation at the time of submission of the application and

- the marketing authorisation holder declares in the application that it will place the medicinal product on the market within 18 months of the marketing authorisation being granted.

(4) If the applicant fails to place the medicinal product concerned on the market within 18 months of the granting of the marketing authorisation, it shall be liable to pay the difference up to the full fee referred to in paragraph one of this Article.

Article 14
(Fees for obtaining a marketing authorisation for veterinary medicinal products)

(1) Fees for obtaining a marketing authorisation for veterinary medicinal products shall be as follows:

1. for obtaining marketing authorisations pursuant to Articles 8, 20, 23 or 25 of Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (hereinafter: Regulation (EU) 2019/6):
   a) NP: 1,000 points;
   b) MRP-CMS: 420 points;
   c) MRP-RMS: 6,000 points;
   d) DCP-CMS: 450 points;
   e) DCP-RMS: 7,000 points;
   f) SRP-RMS: 3,350 points;

2. for obtaining marketing authorisations pursuant to Article 22 of Regulation (EU) 2019/6:
   a) NP: 800 points;
   b) MRP-CMS: 380 points;
   c) MRP-RMS: 5,000 points;
   d) DCP-CMS: 420 points;
   e) DCP-RMS: 5,500 points;
   f) SRP-RMS: 2,800 points;

3. for obtaining marketing authorisations pursuant to Articles 18 or 19 of Regulation (EU) 2019/6:
   a) NP: 700 points;
   b) MRP-CMS: 360 points;
   c) MRP-RMS: 5,000 points;
   d) SRP-RMS 2,700 points;
   e) DCP-CMS: 380 points;
   f) DCP-RMS: 5,800 points;

4. for obtaining marketing authorisations pursuant to Article 21 of Regulation (EU) 2019/6:
   a) NP: 200 points;
   b) MRP-CMS: 200 points;
   c) MRP-RMS: 3,500 points;
   d) SRP-RMS 2,700 points;
   e) DCP-CMS: 200 points;
   f) DCP-RMS: 4,600 points.

(2) Fees for the acquisition of marketing authorisation for a medicinal product regardless of the type of procedure with all legal bases for medicinal products that contain active substances and are currently placed on the market for the needs of market supply as indispensable and essential medicinal products without a marketing authorisation for a medicinal product and which in the previous

year were marketed based on an authorisation for entry and import shall be 50% lower than the fees referred to in the preceding paragraph.

Article 15

(Fees for line extension of the marketing authorisation for ~~a~~ medicinal products for human use)

(1) Fees for the line extension of marketing authorisation for medicinal products for human use shall be as follows:

1. NP: 1,320 points;
2. MRP-CMS: 615 points;
3. DCP-CMS: 615 points;
4. MRP-RMS: 3,145 points;
5. DCP-RMS: 3,875 points.

(2) Notwithstanding the preceding paragraph, the fee for the extension of a marketing authorisation for a medicinal product shall be reduced by 50% if:

- the medicinal product, with its active ingredient, pharmaceutical form and strength, is included in the list of essential medicinal products or indispensable medicinal products;
- the medicinal product has been brought in or imported in accordance with paragraph three of Article 20 of the Act during the 18 months preceding the submission of the application in question;
- there is no medicinal product with the same active substance in the same strength and pharmaceutical form with a marketing authorisation in circulation at the time of submission of the application and
- the marketing authorisation holder declares in the application that it will place the medicinal product on the market within 18 months of the marketing authorisation being granted.

(3) If the applicant fails to place the medicinal product concerned on the market within 18 months of the granting of the marketing authorisation, it shall be liable to pay the difference up to the full fee referred to in paragraph one of this Article.

Article 16

(Fees for renewal of a marketing authorisation for medicinal products for human use)

Fees for renewal of a marketing authorisation for medicinal products for human use shall be as follows:

1. NP: 400 points;
2. MRP/DCP-CMS: 255 points;
3. MRP/DCP-RMS: 2,100 points.

Article 17

(Fees for renewal of a marketing authorisation for veterinary medicinal products for the limited market and in exceptional cases)

Fees for renewal of a marketing authorisation for veterinary medicinal products for the limited market and in exceptional cases shall be as follows:

1. NP: 300 points;
2. MRP/DCP-CMS: 250 points;
3. MRP/DCP-RMS: 2,350 points.

Article 18

(Fees for type I and II variations of medicinal products for human use)

Fees for type I and type II variations for medicinal products shall refer only to medicinal products for which marketing authorisations were obtained in the Republic of Slovenia. If the application is submitted as a grouped variation applicable to several marketing authorisations or worksharing, the fee for the grouped variation or worksharing shall be observed at all times. One marketing authorisation according to this Article shall include a medicinal product of all strengths, pharmaceutical forms or packaging as determined by the root or the main part of the number of the marketing authorisation. Fees shall be as follows:

1. for announcing a type IA variation:
   - NP: 50 points;
   - MRP/DCP-CMS: 30 points;
   - MRP/DCP-RMS: 310 points;

2. for announcing a type IB variation:
   - NP: 110 points;
   - MRP/DCP-CMS: 110 points;
   - MRP/DCP-RMS: 685 points;

3. for the approval of a type II variation:
   - NP: 260 points;
   - MRP/DCP-CMS: 140 points;
   - MRP/DCP-RMS: 1,300 points;

4. in grouping of variations in accordance with Article 7 and 13d of Commission Regulation (EC) No. 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products (OJ L 334, 12.12.2008, p. 7) last amended by Commission Regulation (EU) No. 2021/756 of 24 March 2021 amending Regulation (EC) No. 1234/2008 concerning the examination of variations in the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products (OJ L 162, 10.5.2021, p.1) (hereinafter: Regulation (EC) No. 1234/2008):

a) in point a) of paragraph two of Article 7 of Regulation (EC) No. 1234/2008 and relating to point a) of paragraph two of Article 13d of Regulation (EC) No. 1234/2008 (announcement of type IA variations for one marketing authorisation): a full fee referred to in point 1 of this Article shall apply for the first variation, and 75% of the total fee referred to in point 1 of this Article for each additional variation to the relevant marketing authorisation, but not more than:
   - in NP: 400 points;
   - in MRP/DCP-CMS: 250 points;
   - in MRP/DCP-RMS: 1,500 points;

b) in point a) of paragraph two of Article 7 of Regulation (EC) No. 1234/2008 and relating to point a) of paragraph two of Article 13d of Regulation (EC) No. 1234/2008 (announcement of type IA variations for several marketing authorisations of the same holder): a full fee in accordance with point 1 of this Article shall apply for the first variation of the first marketing authorisation, 75% of the total fee referred to in point 1 of this Article for further variations of the first marketing authorisation, and 75% of the total fee for the same variations to each additional marketing authorisation calculated for the variations of the first marketing authorisation, but not more than:
   - in NP: 400 points;
   - in MRP/DCP-CMS: 250 points;
   - in MRP/DCP-RMS: 1,500 points;

c) in point b) of paragraph two of Article 7 of Regulation (EC) No. 1234/2008 and relating to point b) of paragraph two of Article 13d of Regulation (EC) No. 1234/2008 (extension of marketing authorisation and subsequent variations): a full fee in accordance with Article 15 of this List of Rates shall apply for a major variation and 75% of the total fee for each additional variation referred to in points 1, 2 or 3 of this Article, but not more than:
   - in NP: 2,000 points;
   - in MRP/DCP-CMS: 1,200 points;
   - in MRP/DCP-RMS: 4,200 points;

č) in point b) of paragraph two of Article 7 of Regulation (EC) No. 1234/2008 and relating to point b) of paragraph two of Article 13d of Regulation (EC) No. 1234/2008 (the variation of type IB or II and subsequent or related variations): a full fee referred to in points 2 or 3 of this

Article shall apply for a major variation and 75% of the total fee for each additional variation referred to in points 1, 2 or 3 of this Article, but not more than:

- in NP: 800 points;
- in MRP/DCP-CMS: 450 points;
- in MRP/DCP-RMS: 3,500 points;

d) in point c) of paragraph two of Article 13d of Regulation (EC) No. 1234/2008 (grouping of variations of type IB or II and subsequent or related variations for several exclusively national marketing authorisations of the same holder): a full fee referred to in points 2 or 3 of this Article shall apply for the first variation of the first marketing authorisation, 75% of the total fee referred to in points 1, 2 or 3 of this Article for subsequent variations of the first marketing authorisation, and 75% of the total fee for the same variations to each additional marketing authorisation calculated for the variations of the first marketing authorisation;

5. notwithstanding the preceding point:

a) regardless of the type of procedure, for a grouped single variation concerning a change in the name or address of a marketing authorisation holder or for a single announcement of a summary of the pharmacovigilance system master file applicable to several medicinal products, even if it concerns only one medicinal product (single marketing authorisation) in the Republic of Slovenia, the fee shall be as follows:

- from 1 to 20 medicinal products: 100 points;
- from 21 to 50 medicinal products: 200 points;
- more than 50 medicinal products: 400 points;

b) for grouped variations concerning a change in the name of a medicinal product for human use in several EU Member States for one marketing authorisation, the fee for a single variation shall be as specified in point 2 of this Article, which also applies in cases when the medicinal product's name in the Republic of Slovenia remains unchanged;

c) for grouped variations concerning a change in the name or address of the marketing authorisation holder in several Member States for a single medicinal product (single marketing authorisation), the fee for a single variation shall be as specified in point 1 of this Article, regardless of whether the name or address of the marketing authorisation holder changes in the Republic of Slovenia or not;

6. in worksharing procedures pursuant to Article 20 of Regulation (EC) No. 1234/2008, a full fee in accordance with points 2 or 3 or point č) of point 4 of this Article shall apply to a variation or variations of the first marketing authorisation in the Republic of Slovenia and 75% of the total fee for every additional marketing authorisation, calculated as per the variation or variations of the first marketing authorisation while taking into account whether the Republic of Slovenia is an RMS or a CMS in the relevant worksharing procedure, but not more than:

- in MRP/DCP-CMS: 780 points;
- in MRP/DCP-RMS: 3,500 points.

Article 19
(Fees for the variation of a marketing authorisation for veterinary medicinal products)

Fees for consideration of a variation of a marketing authorisation for veterinary medicinal products shall refer only to medicinal products for which marketing authorisations were obtained in the Republic of Slovenia. If the application is filed as a grouped variation applicable to several marketing authorisations or work-sharing, the fee for the grouped variation or work-sharing shall be observed at all times. Fees shall be as follows:

1. for the approval of variations not requiring assessment (VRNA):

- NP: 30 points;
- MRP/DCP-CMS: 30 points;
- MRP/DCP-RMS: 400 points;

2. for the approval of variations requiring assessment (VRA):

- NP: 165 points;
- MRP/DCP-CMS: 165 points;
- MRP/DCP-RMS: 1,300 points;

3. for the grouping of variations requiring assessment in accordance with Article 64 of Regulation (EU) 2019/6 a full fee referred to in point 2 of this Article shall apply for the first variation and 75% of the total fee for each additional variation referred to in point 2 of this Article, but not more than:
- in NP: 600 points;
- in MRP/DCP-CMS: 550 points;
- in MRP/DCP-RMS: 3,000 points;

4. notwithstanding the preceding point, for a variation concerning a change in the name or address or contact details of a marketing authorisation holder, or for a variation concerning a change in the name or address or contact details of the qualified person responsible for pharmacovigilance, or for a variation concerning a change in the location of the main dossier on a pharmacovigilance system applicable to several medicinal products, the maximum fee shall be as follows:
- from 1 to 20 medicinal products: 100 points;
- from 21 to 50 medicinal products: 200 points;
- more than 50 medicinal products: 400 points;
- MRP/DCP-RMS: 2,500 points;

5. in work-sharing procedures pursuant to Article 65 of Regulation (EC) 2019/6, a full fee in accordance with points 2 or 3 of this Article shall apply to a variation in the first marketing authorisation and 75% of the total fee for every additional marketing authorisation, calculated as per the variation or variations of the first marketing authorisation while taking into account whether the Republic of Slovenia is an RMS or a CMS in the relevant work-sharing procedure, but not more than:
- in MRP/DCP-CMS: 780 points;
- in MRP/DCP-RMS: 3,500 points;

6. for the consideration of variations requiring assessment and requiring a new marketing authorisation (addition of strength or pharmaceutical form):
- NP: 600 points;
- MRP-CMS: 250 points;
- DCP-CMS: 280 points;
- MRP/DCP-RMS: 2,500 points.

Article 20
(Fees for the transfer or cessation of validity of a marketing authorisation for medicinal products for human use)

Fees for the transfer or cessation of a marketing authorisation at the request of the marketing authorisation holder shall be as follows:
1. for the transfer of marketing authorisation to another legal or natural entity: 70 points;
2. maximum fees for a simultaneous transfer of several marketing authorisations to another legal or natural entity: 280 points;
3. for the cessation of marketing authorisation at the request of the marketing authorisation holder for an individual pharmaceutical form or strength: 20 points.

Article 21
(Fees for the transfer or cessation of validity of a marketing authorisation for a veterinary medicinal product)

Fees for the transfer and termination of a marketing authorisation at the request of the holder of a marketing authorisation for a veterinary medicinal product shall be as follows:
1. for the transfer of marketing authorisation to another legal or natural entity: 50 points;
2. maximum fees for a simultaneous transfer of several marketing authorisations to another legal or natural entity: 200 points;
3. for the termination of marketing authorisation at the request of the holder of a marketing authorisation for an individual pharmaceutical form or strength: 20 points.

Article 22
(Fees for the PSUR assessment)

(1) The fee for the assessment of the regular Periodic Safety Update Report (PSUR) for a medicinal product for human use – national procedure (NP) shall be 755 points.

(2) The fee for the assessment of the Periodic Safety Update Report (PSUR) for a medicinal product for human use that is included in PSUR single assessment (PSUSA) shall not be charged.

Article 23
(Fees for a review of educational materials for safe and effective use of medicinal products and for other amendments to product information on a medical product)

(1) Fees for a review of educational materials for safe and effective use of medicinal products shall be as follows:

1. for new educational materials: 305 points;
2. for updating training materials: 225 points.

(2) The fee for announcing changes to package leaflet and labelling that are not associated with changes to the summary of product characteristics for an individual pharmaceutical form or strength shall be 15 points.

(3) Fees for variations in place or manner of dispensing a medicinal product for human use shall be as follows:

1. for the variation of medicinal product classification in terms of the place of dispensing it: 110 points;
2. for the variation of medicinal product classification in terms of the manner of its dispensing: 260 points.

(4) The fee for approving advertising, if this was not decided as part of an application for the obtaining or maintenance of a marketing authorisation, shall be 15 points.

(5) Fees for reviewing the video content of package leaflets in conjunction with summaries of product characteristics and package leaflets shall be 110 points.

Article 24
(Fees for mutually interchangeable medicinal products)

The fee for considering an application for establishing the interchangeability of medicinal products under an independent procedure for establishing interchangeability shall be 100 points.

Article 25
(Fees for herbal medicinal products with effectiveness proven in clinical trials)

Fees for the obtaining, line extension, renewal, variation, transfer and withdrawal of a marketing authorisation for a herbal medicinal product with effectiveness proven in clinical trials shall be as follows:

1. for obtaining marketing authorisations pursuant to Articles 44 or 49 of the Act:
- NP: 1,030 points;
- MRP-CMS: 510 points;
- MRP-RMS: 5,985 points;
- RUP-RMS: 4,000 points;
- DCP-CMS: 510 points;
- DCP-RMS: 6,990 points;

2. for obtaining marketing authorisations pursuant to Article 47 of the Act:
- NP: 1,000 points;
- NP – if there is an EC Monograph; 750 points;
- MRP-CMS: 510 points;
- MRP-RMS: 5,695 points;
- RUP-RMS: 3,700 points;
- DCP-CMS: 510 points;
- DCP-RMS: 6,420 points;

3. for obtaining marketing authorisations pursuant to Article 50 of the Act:
- NP: 325 points;
- MRP-CMS: 310 points;
- MRP-RMS: 2,580 points;
- RUP-RMS: 1,700 points;
- DCP-CMS: 310 points;
- DCP-RMS: 4,190 points;

4. for a line extension of marketing authorisation for a medicinal product:
- NP: 660 points;
- MRP/DCP-CMS: 370 points;
- MRP-RMS: 3,145 points;
- DCP-RMS: 3,875 points;

5. for the renewal of a marketing authorisation for a medicinal product:
- NP: 400 points;
- MRP/DCP-CMS: 255 points;
- MRP/DCP-RMS: 2,100 points;

6. fees for the consideration of type I and II variations of a marketing authorisation shall be equal to the fees referred to in Article 18 hereof;

7. for other variations of the medicinal product information shall be the same as the fees referred to in paragraphs two, three, four and five of Article 23 hereof;

8. fees for the transfer or termination of a marketing authorisation at the request of the marketing authorisation holder shall equal the fees referred to in Article 20 hereof.

Article 26
(Fees for traditional herbal medicinal products)

Fees for the approval, line extension, renewal, variation, transfer and **cessation of validity** of a marketing authorisation for a traditional herbal medicinal product in a simplified procedure shall be as follows:

1. for obtaining a marketing authorisation for a medicinal product:
- NP pursuant to paragraph two of Article 52 of the Act if there is no EC monograph or if additional data are submitted: 600 points;
- NP pursuant to paragraph two of Article 52 of the Act in accordance with the EC monograph: 500 points;
- MRP and DCP-CMS: 300 points;
- MRP-RMS: 4,000 points;
- RUP-RMS: 2,700 points;
- DCP-RMS: 4,500 points;

2. for a line extension of marketing authorisation for a medicinal product:
- NP: 500 points;
- MRP/DCP-CMS: 250 points;
- RUP-RMS: 1,400 points;
- MRP/DCP-RMS: 2,000 points;

3. for the renewal of a marketing authorisation for a medicinal product:
- NP: 300 points;
- MRP/DCP-CMS: 160 points;
- MRP/DCP-RMS: 1,200 points;

4. fees for the consideration of type I and II variations of a marketing authorisation shall amount to 70% of the fees from Article 18 hereof;

5. for other variations of the medicinal product information shall be the same as the fees referred to in paragraphs two, three, four and five of Article 23 hereof;

6. fees for the transfer or termination of a marketing authorisation at the request of the marketing authorisation holder shall equal the fees referred to in Article 20 hereof.

Article 27
(Fees for homeopathic medicinal products for human use)

Fees for the obtaining, renewal, amendment, transfer and withdrawal of a marketing authorisation for a homeopathic medicinal product shall be as follows:

1. for obtaining a marketing authorisation for a homeopathic medicinal product in a simplified procedure that contains a single homeopathic stock associated with one pharmaceutical form – NP: 200 points;

1a. for obtaining a marketing authorisation for a homeopathic medicinal product in a simplified procedure that contains a single homeopathic stock where 5 simultaneous applications are submitted by the same manufacturer, in the same pharmaceutical form - NP 120 points/per application;

2. for obtaining a marketing authorisation for a homeopathic medicinal product in a simplified procedure that contains a single homeopathic stock associated with one pharmaceutical form – MRP/DCP-CMS: 100 points;

3. for obtaining a marketing authorisation for a homeopathic medicinal product in a simplified procedure that contains a single homeopathic stock associated with one pharmaceutical form – MRP/DCP-RMS: 3,500 points;

4. for obtaining a marketing authorisation for a homeopathic medicinal product in a simplified procedure that contains two to three homeopathic stocks associated with one pharmaceutical form – NP: 500 points;

5. for obtaining a marketing authorisation for a homeopathic medicinal product in a simplified procedure that contains two to three homeopathic stocks associated with one pharmaceutical form – MRP/DCP-CMS: 300 points;

6. for obtaining a marketing authorisation for a homeopathic medicinal product in a simplified procedure that contains two to three homeopathic stocks associated with one pharmaceutical form – MRP/DCP-RMS: 4,240 points;

7. for obtaining a marketing authorisation for a homeopathic medicinal product in a simplified procedure that contains more than three homeopathic stocks associated with one pharmaceutical form – NP: 900 points;

8. for obtaining a marketing authorisation for a homeopathic medicinal product in a simplified procedure that contains more than three homeopathic stocks associated with one pharmaceutical form – MRP/DCP-CMS: 700 points;

9. for obtaining a marketing authorisation for a homeopathic medicinal product in a simplified procedure that contains more than three homeopathic stocks associated with one pharmaceutical form – MRP/DCP-RMS: 4,655 points;

10. for the renewal of a marketing authorisation for a homeopathic medicinal product referred to in points 1, 4, 5, 7 and 8 of this Article: 170 points;

11. for the renewal of a marketing authorisation for a homeopathic medicinal product referred to in point in points 1, 1a and 2 of this Article: 80 points;

12. for the renewal of a marketing authorisation for a homeopathic medicinal product referred to in points 3, 6 and 9 of this Article: 1,000 points;

13. for the variation of a marketing authorisation for a homeopathic medicinal product referred to in points 4, 5, 7 and 8 of this Article: 90 points;

14. for changing a marketing authorisation for a homeopathic medicinal product referred to in points 1, 1a and 2 of this Article: 70 points;

15. for changing a marketing authorisation for a homeopathic medicinal product referred to in points 3, 6 and 9 of this Article: 1,000 points;

16. for the transfer or termination of a marketing authorisation at the request of the marketing authorisation holder shall equal the fees referred to in Article 20 hereof;

17. for announcing an additional degree of dilution in the context of a marketing authorisation for a homeopathic medicinal product: 5 points;

18. for the issue of a marketing authorisation for a homeopathic medicinal product in accordance with paragraph one of Article 53 of the Act shall equal the fees referred to in Article 13 hereof.

Article 28
(Fees for homeopathic veterinary medicinal products)

(1) Fees for the registration and variation of the registration of a homeopathic veterinary medicinal product shall be the same as those provided in Article 27 of this Tariff.

(2) Fees for terminating the registration of a homeopathic medicinal product at the request of the medicinal product registration holder shall equal the fees referred to in Article 21 hereof.

Article 29
(Fees for a temporary marketing authorisation or the entry or import of medicinal products with no marketing authorisation)

(1) Fees relating to the issue of a temporary marketing authorisation for the entry or import of medicinal products with no marketing authorisation shall be as follows:

1. for the issue of an authorisation for an individual medicinal product (pharmaceutical form, strength, packaging) in urgent cases of individual treatment: 10 points;
2. for the issuance of an authorisation for an individual medicinal product (pharmaceutical form, strength, packaging) from the list of essential or indispensable human medicinal products: 30 points;

2.a for the issuance of an authorisation for an individual medicinal product (pharmaceutical form, strength, packaging) from the list of essential or indispensable veterinary medicinal products: 10 points;

3. for the issue of an authorisation for an individual medicinal product (pharmaceutical form, strength, packaging) in exceptional cases in the interest of public health protection: 10 points;
4. for the issue of an authorisation for an individual medicinal product (pharmaceutical form, strength, packaging) for medicinal products financed from budgetary resources: 10 points;
5. for the issue of an authorisation for an individual medicinal product (pharmaceutical form, strength, packaging) for veterinary medicinal products upon the occurrence of epizootic diseases: 10 points;
6. for the issue of an authorisation for import or entry of a medicinal product based on an annual tender of necessary quantities of medicinal products: 25 points.

(2) Notwithstanding points 1, 2, 3 and 4 of the preceding paragraph, the fee shall be 30 points for:

1. the issue of a temporary marketing authorisation and an authorisation for the entry or import of a particular group of allergy tests or allergenic extracts,
2. the issue of a temporary marketing authorisation and an authorisation for the entry or import of radiopharmaceuticals at the level of a particular medicinal product in all strengths, pharmaceutical forms and packaging.

Article 30
(Fees for the issue of an authorisation for the entry or import and removal or export of illicit drugs in groups II and III and for sealing the register of medicinal products, which are illicit drugs in groups II, III a and III c)

(1) The fee relating to the issue of an authorisation for the entry or import and removal or export of medicinal products or active substances that are illicit drugs in groups II and III shall amount to 10 points for an individual medicinal product (pharmaceutical form, strength, packaging) or active substance.

(2) The fee for sealing any record books on medicinal products that are illicit drugs in groups II, III a and III c shall amount to 5 points.

Article 31
(Fees for a marketing authorisation for a parallel-imported medicinal product and a certificate on the parallel distribution of medicinal products)

Fees for the issue, renewal, variation and termination of a marketing authorisation for a parallel imported medicinal product shall be as follows:

1. for the issue, renewal, variation and termination of a marketing authorisation for a parallel-imported medicinal product for human use:
- issue: 530 points;
- renewal: 305 points;
- variation: 150 points;
- termination at the applicant's proposal: 25 points;

2. for the issue, renewal, variation and termination of a marketing authorisation for a parallel-imported veterinary medicinal product:
- issue: 300 points;
- renewal: 150 points;
- variation: 80 points;
- termination at the applicant's proposal: 20 points;

3. maximum fees for the issue, renewal, variation and termination of a marketing authorisation for parallel-imported medicinal products, for additional pharmaceutical forms, strengths or packaging within a single application shall be as follows:
- issue: 1,100 points;
- renewal: 610 points;
- variation: 300 points;
- termination at the applicant's proposal: 50 points;

4. for the issue of a confirmation on the receipt of an announcement on the parallel distribution of an individual medicinal product (every pharmaceutical form, strength or packaging): 25 points.

Article 32
(Fees for the approval of individual exemptions from the marketing authorisation)

(1) Fees for the issue of an approval of an individual deviation from the marketing authorisation for an individual medicinal product (pharmaceutical form, strength, packaging): 200 points.

(2) The fee for the issue of an approval of an individual deviation from the marketing authorisation for veterinary medicinal products shall be reduced by 50% if the authority responsible for veterinary medicine issues a written opinion on the necessity of such medicinal product in the interest of protecting public health.

Article 33
(Fees for different labelling of medicinal products)

(1) The fee relating to the issue of an approval for the use of foreign-language-labelled packaging or for the use of foreign-language-labelled packaging with a label in Slovenian in accordance with paragraph five of Article 87 of the Act shall amount to 15 points for each pharmaceutical form and strength of a medicinal product.

(2) The fee relating to the issue of an approval for the use of foreign-language-labelled packaging or for the use of foreign-language-labelled packaging with a label in Slovenian in accordance with the regulation governing the implementation of Regulation (EU) 2019/6 shall amount to 15 points for each pharmaceutical form and strength of a medicinal product.

Article 34
(Fees for the determination of the elements in the blue box and the national identifier of medical products for which the marketing authorisation was obtained under the centralised procedure)

Fees for the determination of the elements in the blue box and the national identifier of medicinal products shall be as follows:

1. 120 points per one marketing authorisation, taking into account that one marketing authorisation in accordance with this Article shall include a medicinal product of all strengths, pharmaceutical forms or packaging as determined by the root or the main part of the number of the marketing authorisation;
2. for the determination of the national identifier of medicinal products: 10 points per packaging.

Article 35
(Fees for the deferment of cancellation of a marketing authorisation)

The fee for the consideration of a proposal to defer the cancellation of a marketing authorisation for a medicinal product that has not been on the market for three consecutive years since the exercise of the authorisation shall be 20 points.

Article 36
(Fee for the approval of conducting a campaign with necessary data on vaccines included in the vaccination and protection products programme)

The fee for approving a campaign with necessary data on vaccines included in the vaccination and protection products programme shall be 300 points.

Article 37
(Fees for product classification)

(1) The fee for the classification of a product and the issue of a decision on classification of the product in accordance with Article 7 of the Act shall be 190 points.

(2) The fee for the classification of a product and the issue of a decision on classification of the product in accordance with the regulation governing the implementation of Regulation (EU) 2019/6 shall be 190 points.

Article 38
(Fees for the determination of an extraordinarily higher allowed price of a medicinal product)

(1) Fees for the determination of an extraordinarily higher price of medicinal products for human use with evidenced total public expenditure above EUR 50,000 for all packagings marketed in the Republic of Slovenia by the applicant, or with an established target population for medicinal product therapeutic indications exceeding 1,000 patients in the Republic of Slovenia, shall be as follows:

1. for the determination of an extraordinarily higher allowed price of a medicinal product – at the level of a particular active substance or particular combinations of active substances (ATC5): 140 points;
2. for the determination of an extraordinarily higher allowed price of a medicinal product – additional pharmaceutical form or strength: 25 points;
3. for the determination of an extraordinarily higher allowed price of a medicinal product – additional packaging: 10 points;
4. for the termination of an extraordinarily higher allowed price of a medicinal product before the expiry of the validity of the price, on the proposal of the person liable: 5 points.

(2) Fees for the determination of an extraordinarily higher price for other medicinal products for Ahuman use shall be as follows:

1. for the determination of an extraordinarily higher allowed price of a medicinal product – at the level of a particular active substance or particular combinations of active substances (ATC5): 70 points;
2. for the determination of an extraordinarily higher allowed price of a medicinal product – additional pharmaceutical form or strength: 15 points;

3. for the determination of an extraordinarily higher allowed price of a medicinal product – additional packaging: 5 points;
4. for the termination of an extraordinarily higher allowed price of a medicinal product at the applicant's proposal: 5 points.

(3) Notwithstanding paragraphs one and two of this Article, the fee for the determination of an exceptional higher authorised price for each group of allergy tests or allergen extracts shall be: 140 points.

Article 39
(Fees for the determination of the maximum allowed price of a medicinal product)

(1) Fees for the determination of the maximum allowed price of a medicinal product for human use shall be as follows:

1. for the determination of the maximum allowed price of a medicinal product at the level of an active substance or combinations of active substances (ATC5), strengths, pharmaceutical forms or packaging: 10 points;
2. for periodic reconciliation and reduction of the maximum allowed price of a medicinal product at the level of an active substance or combinations of active substances (ATC5), strengths, pharmaceutical forms or packaging: 6 points.

(2) Notwithstanding paragraph one of this Article, the fee for the initial determination of the maximum allowed price and for the periodic reconciliation or reduction of the maximum allowed price for a particular group of allergy tests or allergen extracts shall be: 50 points.

Article 40
(Fee for announcing a business donation of a medicinal product)

The fee for announcing a business donation of a medicinal product (any pharmaceutical form, strength or packaging) shall be 40 points.

Article 41
(Fees for the issue of an authorisation relating to human tissue and cell supply)

(1) Fees for the issue, variation and withdrawal of an authorisation for human tissue and cell supply shall be as follows:

1. for the issue of an authorisation for human tissue and cell supply per commission member per day of verification at the applicant's premises: 245 points;
2. for the consideration of a variation when a repeated verification at the applicant's premises is necessary and the variation requires an amendment to the authorisation for human tissue and cell supply per day of inspection by the committee: 225 points;
3. for the consideration of a variation when a repeated verification at the applicant's premises is not necessary and the variation requires an amendment to the authorisation for human tissue and cell supply: 75 points;
4. for the assessment of compliance with the requirements for performing the activity of supply with human tissues and cells when a repeated verification at the applicant's premises is necessary and the variation does not require an amendment to the authorisation for human tissue and cell supply per day of inspection by the committee: 225 points;
5. for the assessment of compliance with the requirements for supplying human tissues and cells when a repeated verification at the applicant's premises is not necessary and the variation does not require an amendment to the authorisation for human tissue and cell supply per committee member drawing up the compliance assessment based on submitted documentation: 75 points;
6. for the withdrawal of an authorisation for human tissue and cell supply upon the proposal of the authorisation holder: 20 points.

(2) Fees for the issue of an authorisation for single entry or import and removal or export of human tissues and entry or import and removal or export of human tissues and cells in urgent cases shall be as follows:

1. for the issue of an authorisation for single entry or import and removal or export of human tissues and cells: 165 points;

2. for the issue of an authorisation for the entry or import and removal or export of human tissues and cells in urgent cases: 115 points.

Article 42
(Fees for the issue of a blood supply authorisation)

Fees for the issue, variation and withdrawal of a blood supply authorisation shall be as follows:

1. for the issue of an authorisation for blood supply per day of verification by the committee: 245 points;
2. for the consideration of a variation when a repeated verification at the applicant's premises is necessary and the variation requires an amendment to the authorisation for blood supply per day of verification by the committee: 225 points;
3. for the consideration of a variation when a repeated inspection at the applicant's premises is not necessary and the variation requires an amendment to the authorisation for blood supply: 75 points;
4. for the assessment of compliance with the requirements for supplying blood when a repeated verification at the applicant's premises is necessary and the variation does not require an amendment to the authorisation for blood supply per day of verification by the committee: 225 points;
5. for the withdrawal of authorisation for blood supply: 40 points.

Article 43
(Fees for the preparation of non-routinely prepared medicinal products for advanced therapy)

Fees for the issue, variation and withdrawal of an authorisation for non-routinely prepared advanced therapy medicinal products shall be as follows:

1. for the issue of the authorisation for non-routinely prepared medicinal products for advanced therapy per day of expert committee inspection at the applicant's premises: 480 points;
2. for the consideration of a variation when a repeated inspection at the applicant's premises is necessary and the variation requires an amendment to the authorisation for non-routinely prepared medicinal products for advanced therapy per day of expert committee inspection at the applicant's premises: 300 points;
3. for the consideration of a variation when a repeated inspection at the applicant's premises is not necessary and the variation requires an amendment to the authorisation for non-routinely prepared medicinal products for advanced therapy at the applicant's premises: 120 points;
4. for the assessment of compliance with the requirements for non-routinely prepared medicinal products for advanced therapy when a repeated verification at the applicant's premises is necessary and the variation does not require an amendment to the authorisation for non-routinely prepared medicinal products for advanced therapy per day of expert committee inspection at the applicant's premises: 300 points;
5. for the withdrawal of authorisation for non-routinely prepared medicinal products for advanced therapy: 40 points.

Article 44
(Fees for the register of doctors or veterinarians)

Fees for the entry into, amendment of an entry in and removal from the register of doctors or veterinarians who use non-routinely prepared advanced therapy medicinal products in their practice shall be as follows:

1. for the entry of a doctor or veterinarian into the register: 20 points;
2. for an amendment to the entry of a doctor or veterinarian in the register: 20 points;
3. for the removal of a doctor or veterinarian from the register: 20 points.

Article 45
(Fees for announcing galenic medicinal products and the approval of risk assessments for the manufacture of galenic medicinal products and for the preparation of extemporaneous medicinal products)

(1) The fee for announcing a particular pharmaceutical form, strength and packaging of a galenic medicinal product shall be 50 points.

(2) The fee for the approval of risk assessment for the manufacture of galenic medicinal products and for the preparation of extemporaneous medicinal products shall be 50 points.

Article 46
(Fees for minor administrative procedures)

(1) The fee for minor administrative procedures not specifically provided for herein shall be 180 points.

(2) The consideration of a variation or the assessment of compliance with the requirements for the manufacture of medicinal products, the wholesale distribution or retail sale in medicinal products, the supply of blood, tissues and cells when an inspection at the applicant's premises is not necessary, the assessment of compliance with the requirements for entry into the register of manufacturers, wholesalers and importers of active substances and other similar procedures shall be considered minor procedures.

Article 47
(Costs of procedure)

(1) If an applicant withdraws their application before the completion of the procedure or if the JAZMP rejects the application, the JAZMP shall charge:

1. 15% of the amount of the fee if the application has not yet been processed (i.e. the review of formal completion of the application or until the submitted notification on the fee payment method);
2. up to 100% of the amount of the fee if the applicant withdraws the application before the completion of the procedure with regard to the scope of acts already performed within the proceedings, which shall be decided by the JAZMP.

(2) The JAZMP shall determine the costs of the administrative procedure in decisions on the termination of the administrative procedure or in the decision on the rejection of the application.

III. PROFESSIONAL TASKS AND SERVICES

Article 48
(Payment obligations, methods and deadline)

(1) Fees for services rendered to users of professional services shall arise upon receipt of the invoice or the payment notification from the JAZMP and they must be paid to the JAZMP sub-account within 15 days.

(2) In the event of non-payment, the JAZMP may charge statutory late payment interest to the applicant.

Article 49
(Expert training, lectures and consultations)

(1) The JAZMP shall charge the user for the participation of its staff in training, lectures, workshops and consultations 30 points per hour and 20 points per hour for each hour of preparation for participation.

(2) Based on a proposal for training, lecture or consultation, the JAZMP shall issue a pro forma invoice.

(3) In addition to the rate referred to in paragraph one of this Article, the user shall be required to settle any costs arising from training, lectures and consultations, which shall include costs pursuant to the regulations governing the reimbursement of costs for staff business trips.

(4) The costs of training, seminars and workshops organised by the JAZMP shall be determined by means of a participation fee.

(5) The aforementioned participation fee shall be determined according to labour costs, the costs of renting premises, costs of producing training materials, and other costs incurred during the implementation of training, seminars or consultations. The JAZMP shall publish information on the amount of the participation fee on its website or on the application for training, seminar or consultation.

Article 50
(Consulting)

(1) The JAZMP shall charge for its consultation 30 points per hour.

(2) Based on a proposal for consultation relating to drafting documentation within the powers of the JAZMP referred to in the preceding paragraph, the JAZMP shall issue a pro forma invoice including an estimated value. The user shall settle 50% of the amount on the pro forma invoice before the consultation starts.

(1) The JAZMP shall issue an invoice with actual hours of work performed.

Article 51
(Specialisation and mentoring of external users)

(1) The JAZMP shall charge 5 points per hour for specialisation or mentoring of external users.

(2) Based on a proposal for specialisation or mentoring, the JAZMP shall issue a pro forma invoice for external users. Participation in the specialisation or mentoring of external users shall not take place until the user confirms the pro forma invoice for specialisation or mentoring.

Article 52
(Travel and other costs of the members of expert and verification committees when performing their tasks)

Alongside the fees from this List of Rates, the applicant shall pay for the costs of expert and verification committee members referred to in Articles 6 and 12 hereof, which shall be charged as prescribed in the regulation governing the reimbursement of costs for business trips.

Article 53
(Publishing)

The JAZMP shall charge for delivering editions of Formularum Slovenicum to users as follows:
1. Formularum Slovenicum – printed edition: 15 points per copy;
2. Formularum Slovenicum – 1 to 5 passwords for an online edition: 17 points per copy;
3. Formularum Slovenicum – 6 to 25 passwords for an online edition: 15 points per copy;
4. Formularum Slovenicum – more than 25 passwords for an online edition: 13 points per copy;
5. The brochure accompanying a presentation of Formularum Slovenicum: 12 points per copy.

Article 54
(Photocopying)

(1) Photocopying, printing and scanning shall be charged by the JAZMP to the user:
1. photocopying, printing – A4, black and white, single-sided: 0.028 point per copy;
2. photocopying, printing – A4, black and white, double-sided: 0.04 point per copy;
3. photocopying, printing – A4, colour, single-sided: 0.12 point per copy;

4. photocopying, printing – A4, colour, double-sided: 0.22 point per copy;
5. scanning – A4, single-sided: 0.024 point per copy;
6. scanning – A4, double-sided: 0.036 point per copy.

(2) The JAZMP shall charge scanning and printing to the user according to the rate for printing.

Article 55
(Issue of additional copies and duplicates, and confirmation of the finality of individual administrative acts)

The issuing of additional copies and duplicates and confirmation of the finality of individual administrative acts shall be charged by the JAZMP to the user:
1. every additional copy of an individual administrative act (decision, notification, certificate etc.): 6 points;
2. the issue of duplicates of individual administrative acts (decision, notification, certificate etc.): 15 points;
3. the confirmation of the finality of individual administrative acts (decision, notification, certificate etc.): 6 points.

Article 56
(Other professional tasks)

The JAZMP may charge for the performance of other professional tasks, which are not governed by this List of Rates, based on calculations, *mutatis mutandis* use of rates for consultations and photocopying and other direct costs.

Article 57
(Issue of reminders for outstanding liabilities)

The JAZMP may charge the debtor 0.4 point for the issue of a reminder for outstanding liabilities.

Appendix 1:

	JAZMP		**Medical Ethics Committee**		**TOTAL FEE**	
Approval of a clinical trial	**Clinical trial**	**Minimal intervention clinical trial**	**Clinical trial**	**Minimal intervention clinical trial**	**Clinical trial**	**Minimal intervention clinical trial**
SLO RMS	1091	727	182	182	**1273**	**727**
SLO CMS	273	182	182	182	**455**	**364**
Approval of a substantial amendment						
SLO RMS - PART I	145	91			**145**	**91**
SLO CMS - PART I	73	55			**73**	**55**
SLO RMS - PART II			55	55	**55**	**55**
SLO CMS - PART II			55	55	**55**	**55**
SLO RMS - PART I and PART II					**200**	**146**
SLO CMS - PART I and PART II					**128**	**110**

The tariff of the Agency of the Republic of Slovenia for medicines and medical devices (Official Gazette of the Republic of Slovenia, No. 209/21) contains the following transitional and final provision:

IV. TRANSITIONAL AND FINAL PROVISION

Article 58
(End of validity)

(1) As of the date of entry into force of this List of Rates, the Tariff of the Public Agency of the Republic of Slovenia for Medicinal Products and Medical Devices (Official Gazette of the Republic of Slovenia [*Uradni list RS*], No. 9/18) shall cease to apply.

(2) The Tariff of the Public Agency of the Republic of Slovenia for Medicinal Products and Medical Devices (Official Gazette of the Republic of Slovenia [*Uradni list RS*], No. 9/18) shall still apply to the procedures which began before the date of the entry into force of this List of Rates or relating to which a legal remedy had already been filed upon the entry into force of this List of Rates.

Article 59
(Start of use)

(1) Article 12 of this List of Rates shall apply from the date of application of the regulation implementing Regulation (EU) No. 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use and repealing Directive 2001/20/EC.

(2) Articles 14, 17 and 19 of this List of Rates shall apply from 28 January 2022.

(3) Paragraph two of Article 33 and paragraph two of Article 37 of this List of Rates shall apply from the date of application of the regulation implementing Regulation (EU) No. 2019/6.

Article 60
(Entry into force)

This tariff shall enter into force on 1 January 2022

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Amendments and additions to the Tariff of the Agency of the Republic of Slovenia for Medicines and Medical Devices (Official Gazette of the Republic of Slovenia, No. 165/22) contain the following transitional and final provision:

TRANSITIONAL AND FINAL PROVISIONS

Article 11
(completion of procedures)

The Tariff of the Agency of the Republic of Slovenia for Medicinal Products and Medical Devices (Official Gazette of the Republic of Slovenia, No. 209/21) shall apply to proceedings initiated prior to the entry into force of these Amendments and additions to the Tariff or in respect of which a legal action has already been filed at the time of the entry into force of these Amendments to the Tariff.

Article 12
(start of force)

These amendments and additions shall enter into force on January 1, 2023.

Franjo Levstek
President of the Council of
the Public Agency of the
Republic of Slovenia for
Medicinal Products and
Medical Devices